Remarks/Arguments

Eighteen (18) claims remain pending in the application: Claims 1-7 and 10-20, of which Claims 1 and 10 are independent. Claims 8 and 9 have been cancelled. Claims 17 -20 have been added, with Claims 17 and 18 depending from Claims 1 and 10, respectively, and Claim 19 depending from Claim 1, and Claim 20 depending from Claim 19. No new matter has been added. Support for new Claims 17 and 18 can be found at least in FIG. 4 and paragraph [0048], and support for new Claims 19 and 20 can be found at least in Claims 8 and 9 as originally filed. Applicant respectfully requests reconsideration of the pending claims, in view of the comments below.

Claim Rejections

The Examiner rejected Claims 1-7 and 10-16 under 35 U.S.C. 103(a) as being unpatentable over King (Patent No. 6,745,079). The Examiner stated that:

> King teaches the uses of an implantable lead and the injection of 4 columbs *(sic)* of charge to elicit the desired neural response. The amount of charge is known from taking the current and multiplying it by the pulse width. (Column 9 lines 20-30). While King does not teach how the amount of charge is determined, it would have been obvious to determine the response empirically, testing on *(sic)* electrode and then setting the others to a comparable charge amount when the tissue is the same type for the same response and testing other electrodes when different tissues and different responses are evoked. Applicant's method is nothing more than the determination of a threshold amount of charge to elicit the desired response by charting the response versus the stimulation and defining a minimum acceptable response as an axis. Such is desired as noted by King to prevent the generation of hydrogen and oxygen gases. Measuring the responses for both positive and negative peaks to determine the optimum charge injection for each so that the stimulation may be altered to reduce polarization is considered obvious.

This rejection is respectfully traversed. King states (Column 9 lines 5-15):

> The electrically conductive area of this electrode 33 should be large enough to allow therapeutic electric currents (typically up to 20 ma) to pass at voltages available from the implanted pulse generator (typically up to 15 Volts). Hence, enough of the distal end of the extendable member must be uninsulated so that the impedance of the member from proximal to distal end is less than 500 Ohms, and potentially less than 100 Ohms, since other parts of the system like the extension and pulse generator and the tissue itself may also have impedance that restricts the amount of current to flow.

It is respectfully submitted that King's description of "allow[ing] therapeutic electric currents (typically up to 20 ma) to pass at voltages available from the implanted pulse generator (typically up to 15 Volts)" does not constitute providing a particular "charge to elicit the desired neural response". The fact that charge can be calculated from current and pulse width, and that King notes that to avoid gas evolution requires sufficient surface area for a given charge (which is a well-known design consideration), does not render the invention obvious.

The present inventor recognized key problems that exist when fitting a patient with a cochlear implant or other multielectrode neural stimulation device, none of which were addressed by King:

- for very young patients or those with impaired communication abilities, objectively-measured neural response is often used in the fitting process, which can be even more time-consuming than normal (paragraphs [0031] and [0034]) ;
- it is common for the pulse widths of stimuli used to elicit the neural response to be different than the pulse widths that are applied to the patient by the operating program of the cochlear implant system during its everyday use (paragraph [0005]);
- it would be advantageous to provide a method whereby a clinician does not need to re-measure neural response values each time a pulse-duration change is made to the patient's program (paragraph [0041]); and
- neural systems are provided with many electrodes, and the number of combinations that need to be tested to determine an optimum safe and efficacious combination for use is almost unmanageable (paragraph [0024]).

Furthermore, the inventor discovered or recognized several key details, which he used to formulate a solution to those problems:

- a threshold neural response can provide a "ball-park" target for stimulation levels, i.e., less than the M levels and greater than the T levels (paragraph [0036]);
- for various pulse widths, adjusting the current to keep the delivered charge the same

achieves the same therapeutic result. For example, when using stimulus pulse widths from 11 μs to 75 μs and adjusting the current amplitude to deliver a charge of 14.6 nC, a psychophysical level of 6.5 on a loudness scale of 1-10 was consistently obtained (paragraph [0038]) ;

- the neural response is a function of charge; it is not an "all-or-nothing" response (measured as peak to peak voltage, FIG. IC);
- applying similar charge to electrodes in similar tissue produces a similar neural response (such as tNRI, FIG. 5); and
- applying similar charge to electrodes in similar tissue produces a similar therapeutic result (such as M, FIG. 5).

Having recognized these key details, the inventor further recognized that there is a relationship between the neural response produced by application of a stimulus of a known charge to one electrode and the therapeutic response produced by application of a stimulus of the same charge to another electrode in similar tissue (paragraph [0007]). Having discovered this relationship, the inventor formulated a solution to the abovedescribed problems, comprising:

- determining a threshold neural response elicited by applying a stimulus to an electrode;
- determining the charge associated with the stimulus; and
- setting program levels of stimuli applied by the implant system during its operation to others of the multiple electrodes to stimuli having approximately the same charge as the charge of the stimulus.

It is submitted that this invention would not have been obvious to one having ordinary skill in the art at the time the invention was made. Applicant's invention provides a method for determining which stimulation level to use on each electrode *without having to measure a response at each electrode* as is common in the art. Because King does not show or suggest the invention as claimed, it is respectfully submitted that the claims are in condition for allowance.

Conclusion

In view of the foregoing, it is respectfully submitted that the rejections should be removed and that the pending claims are in condition for allowance. An indication of allowability of Claims 1-7 and 10-20 at an early date is thus earnestly solicited.

The Examiner is invited to telephone the undersigned, Liz Bush, at (661) 362-7504 should any issues remain after consideration and entry of this response, in order to permit early resolution of such issues.

Respectfully Submitted,

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